Senate Community Affairs Committee
Inquiry into Therapeutic Goods Amendment (Repeal of Ministerial Responsibility for RU486)Bill 2005
Supplementary Submission from Dr Elvis Seman, Consultant Gynaecologist,
15th January 2005

Further to my submission to the Senate Inquiry dated 8.1.06, I wish to make a supplementary submission to clarify & strengthen the important messages about RU486. My comments will be limited to the role of RU486 in voluntary termination of pregnancy, & the proposed repeal of Ministerial responsibility in relation to this indication.

I have been a consultant gynaecologist in private & public hospital practice since 1991. Based in Southern Adelaide, I have visited rural S.A. & Qld for over a decade, & head a urogynaecology clinic in a large university-affiliated teaching hospital (Flinders Medical Centre). In our department the majority of obstetricians & gynaecologists are prochoice & vocally so, & a silent minority do not provide termination of pregnancy services. I belong to this minority group as well as being a member of the Australian Medical Association, National Association of Obstetricians & Gynaecologists, & am a Fellow of both the Royal Australian & New Zealand College of Obstetricians & Gynaecologists and the London-based Royal College of Obstetricians & Gynaecologists.

Irrespective of whether a doctor is prochoice or prolife, I believe that none of us want to see a mother come to harm, and it is on this common premise of avoiding harm that I wish to base my views. The two things that concern me most about chemical abortion with RU486 are that we have only heard one side of the story & almost nothing about the evidence-based disadvantages of it in comparison with surgical abortion and, most importantly, chemical abortion has been promoted as being of equivalent safety to early surgical abortion when current US data show a 3 to 17 times higher death rate from early chemical abortion.

As a member of RANZCOG, NASOG & the AMA, I am disappointed these organizations have not fairly represented all of their members evidence-based views on RU486, not just the views of members in favour of it. Consequently, I have written to the state & federal presidents of the AMA, as well as the RANZCOG president, pointing out this oversight (copies of letters sent to Senate Inquiry on 13.1.06).

Professor Greene in the December 2005 edition of the New England Journal of Medicine quotes a maternal death rate of 1.7/100,000 for chemical abortion versus 0.1 for early surgical abortion. This means that for a country performing say 90,000 early abortions per year, one would expect one maternal death from surgical termination every 11 years, whilst during the same interval one would expect about 17 deaths from chemical abortion. Analysis of deaths associated with RU486-induced abortion in the USA shows that 5 were linked to Clostridium sordellii, & one to a ruptured ectopic pregnancy. Careful analysis of these cases reveals why they are associated with chemical abortion rather than surgical abortion. Firstly women with fatal clostridial sepsis presented with symptoms which are seen commonly during chemical abortion, making early recognition & treatment difficult, & secondly none of them had retained products of conception on autopsy & they died rapidly, implying their immune response may have been compromised by the drugs administered. Women undergoing surgical abortion routinely

have confirmation that a pregnancy has been removed from the womb, either by inspection of the tissue in the operating theatre or by a pathologist . No such check is possible with chemical abortion and, as the 2 drugs used do not reliably terminate ectopic pregnancies, one expects a delay in diagnosis & treatment of this potentially fatal condition. This explains why the FDA adverse events reports between 2000 & 2004 tabled that 11 out of 17 women with an undiagnosed ectopic pregnancy had ruptured by the time of diagnosis. This analysis leads me to conclude that chemical abortion is less safe that surgical abortion, & it should not be offered as an alternative to surgical abortion.

During my specialist training in obstetrics & gynaecology I will never forget a case report of a baby delivered with hydrocephalus and growth retardation after the mother discontinued a midtrimester termination (Wood P et al, Growth retardation and fetal hydrocephalus developing after discontinuation of a mid-trimester termination procedure. Case report. British Journal of Obstetrics & Gynaecology 1987; 94:372). Whilst the drugs and the gestation are different for RU486 abortion, what really struck me about this case was that any termination method which involves more than one treatment has the potential for this type of devastating complication. Surgical termination doesn't. The foetal malformation rate in pregnancies continuing after RU486 is reported to be at least 23%.As every doctor has had patients who fail to attend for followup, even with life-threatening conditions, I fear that this complication will not be preventable.

Finally, I wish to address the question of ministerial responsibility for approval of RU486 for pregnancy termination. Had it not been for this Senate Inquiry I fear that a balanced presentation of the evidence for & against RU486 would not have taken place. The major organizations involved in presenting evidence on RU486 (AMA, RANZCOG & NASOG) have not highlighted the potential dangers & disadvantages of chemical over surgical abortion, nor have they fairly represented the evidence-based opinions of all of their members. Had this responsibility been delegated to the TGA it is likely that opinions from gynaecologists such as myself would not have been heard, & a decision would have been based on one-sided information. RU486 should never be approved for this purpose by an unelected official without the Minister of Health taking responsibility & Parliament knowing about it.

In closing, I wish to end on a note of hope. The RU486 debate has allowed us to "take stock" of where we are with abortion in Australia. The only people who dislike terminations more than the doctors doing them are the 90,000 Australian women who each year feel they have no other alternative. After this inquiry, and irrespective of the outcome, we need to focus our attention on the pressures causing Australian women to seek abortion & start providing viable alternatives. Selena Ewing's 2005 evidence-based review of termination of pregnancy proposes a research agenda worthy of our attention.

Yours faithfully,

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